REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. §1.112, are respectfully requested in light of the following remarks.

FOREIGN PRIORITY

Applicants thank the Examiner for acknowledging their claim for foreign priority and the certified copy of the priority document (filed with the International Bureau and transmitted by the International Bureau to the USPTO in this national phase application).

INFORMATION DISCLOSURE STATEMENTS

Applicants also thank the Examiner for considering their first Information Disclosure Statement (IDS) and documents cited therein, and for returning a fully initialed copy of their Form PTO-1449. A second IDS is submitted herewith.

STATUS OF CLAIMS AND SUPPORT FOR AMENDMENTS MADE

Claims 1-17 remain in this application. Claims 18-22 were previously cancelled.

Claim 9 has been amended in accord with page 10, lines 12-18 of the specification.

Claim 10 has been amended in accord with page 10, lines 35-39 of the specification.

Claim 12 has been amended in accord with page 15, lines 2-5 of the specification.

Thus, no new matter has been introduced.

CLAIM REJECTIONS - 35 U.S.C. §112

Claim 10 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite because of the use of the trademark/tradename Gelucire 50/13 therein. The trademark/tradename has been replaced in Claim 10 by a definition of the material used, said definition being as set forth in the original specification. Accordingly, the amended language of Claim 10 is no longer indefinite and the §112 rejection of Claim 10 has been rendered moot.

Claim 12 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite as to the location of the surfactant. The claim has been amended to specify that the flexible and deformable film (ii) optionally comprises a surfactant, an antistat and/or a lubricant, in accord with page 15 of the specification. Thus, the amended claim can no longer be criticized as indefinite.

In view of the foregoing, it is believe that the claims are free of the 35 U.S.C. §112, second paragraph, rejection. Withdrawal of the rejection is in order and is earnestly solicited.

CLAIM REJECTIONS - 35 U.S.C. §103

Claims 1-17 have been rejected under 35 U.S.C. §103(a) as being unpatentable over the combined disclosures of Chen et al. U.S. Patent No. 6,544,556 in view of Saslawski et al. U.S. Patent No. 6,426,087. Applicants submit that this rejection cannot be maintained against the present claims.

The aim of the present invention is to provide gastroresistant spheroids which are directly tabletable, i.e., with less than 5% of auxiliary substances (page 5, lines 3-6 of the specification), and whose release profile is maintained, that is, the enteric

coating does not crack during tableting. See page 4, lines 14-28 of the specification; see also page 10, line 12 to page 11, line 12 of the specification.

The inventors have thus found that the addition of polyglycosylated glycerides in the enteric coating allows formation of a flexible and deformable film that does not crack during tableting, even with less than 5% of the auxiliary substances, allowing maintenance of the protective function of the enteric coating in the stomach. Neither Chen et al. U.S. Patent No. 6,544,556 nor Saslawski et al. U.S. Patent No. 6,426,087 describes such a use of polyglycosylated glycerides, separately or in combination.

The Chen et al. patent relates to an oral solid dosage form of an NSAID (non-steroidal anti-inflammatory drug) and a proton pump inhibitor. The aim of the Chen et al. patent is to provide an NSAID formulation without the undesirable stomach discomfort and other side effects typically associated with NSAID therapy (col. 3, lines 24-27).

Thus, a person skilled in the art who wants to prepare gastroresistant spheroids which are directly tabletable would not be incited to use the knowledge of Chen et al. This is particularly true in light of the fact that all of Chen et al.'s examples concern either capsules containing enteric coated pellets or tablets coated with an enteric layer, not tablets obtained by compression of enteric coated spheroids.

It is, however, specified in the Chen et al. specification that the enteric coated substrates can be compressed into a multiple unit tableted dosage form, but in this case the substrates have to be mixed with tablet excipients (column 10, lines 41-44), which is contrary to the aim of the present invention.

Chen et al. also mention use of a plasticizer in the enteric coating layer, but glycosylated glycerides are never mentioned as suitable plasticizers (column 10, lines 10-26). Thus, the teachings of Chen et al. do not lead the ordinary skilled person to use polyglycosylated glycerides in an enteric coating to obtain a flexible and deformable film which does not crack during tableting.

Furthermore, such knowledge is not contained in the Saslawski et al. patent either.

The Saslawski et al. patent relates to an orally administrable galenic form comprising an absorption-promoting agent such as polyglycosylated glycerides. Thus, Saslawski et al. use polyglycosylated glycerides as an absorption-promoting agent, i.e., as an agent allowing improved absorption of active ingredients which are hydrophilic or ionizable in physiological media (column 1, lines 10-19), and not as an additive in enteric coating to form a flexible and deformable film which does not crack during tableting.

According to the method of preparation of tablets described in the Saslawski et al. patent (column 9, lines 35-56), the absorption-promoting agent is mixed with the active principles and other excipients before being compressed. Thus, the absorption-promoting agent is present in the core of the oral dosage form with the active ingredient, not in the coating.

Furthermore, all of the Examples of the Saslawski et al. patent concern either capsules filled with a semisolid matrix or with microgranules, or tablets obtained by compression of a base granule, the tablets being optionally film coated, but not the granules. Thus, there is nothing to lead one of ordinary skill to combine the teachings of the two references. And, indeed, combining the references would not

arrive at the present invention because, when combined, the polyglycosylated glycerides would necessarily be present in the core with the active ingredient to be in accord with Saslawski et al. Neither reference teaches or suggests use of polyglycosylated glycerides in the enteric coating to form a flexible and deformable film which does not crack during tableting.

In view of the foregoing, the teachings of Chen et al. and Saslawski et al. separately, or in combination, do not suggest doing what applicants did. Withdrawal of the record §103 rejection is believed to be in order and is earnestly solicited.

CONCLUSION

In light of the foregoing, this application is believed to be free of all record rejections. Further, favorable action in the form of a Notice of Allowance is believed to be next in order and is earnestly solicited.

Respectfully submitted,

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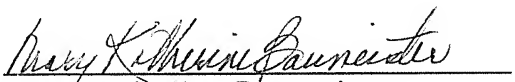
Date: January 8, 2009

By: 
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